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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,786	07/12/2001	Edward F. Patz JR.	DUKE-227	6628

7590 12/16/2002

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EXAMINER

DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/16/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/902,786

Applicant(s)

PATZ ET AL.

Examiner

Deborah A Davis

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 10-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Election/Restrictions

1. Applicant's election with traverse of Group 1 in Paper No. 5 is acknowledged.

The traversal is on the ground(s) that the search and examination of the entire application could be made without serious burden. This is not found persuasive because even though some of the groups are placed in the same class and subclass, the search for each of the groups require a different search strategy on commercial data bases since they recite some limitations that do not overlap.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a) because they fail to indicate the protein profiling system, label 100, in Figure I, as described in the specification, page 8, line 47. Please make appropriate correction.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1641

4. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Yates et al (USP#5,538,897).

Yates et al teaches the use of mass spectrometry fragmentation patterns of peptides to identify amino acid sequences in databases. A peptide is analyzed by tandem mass spectrometer to yield a peptide fragment mass spectrum. A protein sequence database or a nucleotide sequence database is used to predict one or more fragment spectra for comparison with the fragment spectrum, as recited in claims 1 and 4 (see abstract). A fractionation unit such as gel filtration chromatography and/or high performance liquid chromatography (HPLC) is used to separate the proteins before being introduced to mass spectrometer (col. 2, lines 51-55). The proteins are separated into fragments to be analyzed by mass spectrometer (col. 2, lines 65-67). The present invention can be used in connection with diagnostic applications such as some forms of cancer, genetic disease and cystic fibrosis as recited in claims 2, 3, 8, and 9 (col. 17, lines 62-67 and col. 18, lines 25-38). According to the definition of Neural Network in the specification, Yates et al describes such a system that provides a protein sequence database that is used to predict one or more fragment spectra for comparison with derived fragment spectrum. The various predicted mass spectra are compared to the experimentally derived fragment spectrum using a "closeness-of-fit measure" preferable calculated with a two-step process, including a calculation of a preliminary score and, for the highest scoring predicted spectra, calculation of a correlation function as recited in claims 4 and 5 (col. 5, lines 1-30, col. 6, lines 38-55 and Figures 6A-6E). The protein data base system assigns peak intensities values to each fragment, which values

Art Unit: 1641

include the predicted mass spectra and the experimentally-derived fragment spectrum as recited in claim 6 (col. 5, lines 53-67).

Conclusion

5. No claims are allowed.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

A. Joseph P. Laurino (WO97/09678) teaches a system for analyzing a set of parameters such as diagnosing biological organs using a neural network that recognizes random input error.

B. Lapointe et al, (WO97/29447) teaches a method for selecting medical and biochemical diagnostic tests using neural network-related application.

C. Donald H. Chace (USP# 6,258,605) teaches a method of screening newborns using electrospray tandem mass spectrometry and a protein database for analyzing samples.

Art Unit: 1641

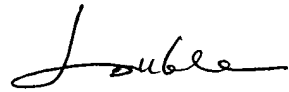
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.



Deborah A. Davis
CM1, 7D16
December 12, 2002



LONG V. LE
SUPERVISORY PATENT EXAMINER
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12/13/02